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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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6 RECORD OF ORAL HEARING

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8 U.S. PATENT AND TRADEMARK OFFICE
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10

11 BEFORE THE BOARD OF PATENT APPEALS
12 AND INTERFERENCES
13
14

15 *Ex parte* WILLIAM F. DEGRADO, GREGORY N. TEW, MICHAEL L.
16 KLEIN, DAHUI LIU, JING YUAN, and SUNGWOOK CHOI
17
18

19 Appeal 2010-005832
20 Application 10/801,951
21 Technology Center 1627
22
23

24 Oral Hearing Held: July 11, 2012
25
26

27 Before JAMES T. MOORE, RICHARD SCHAFER, and HUBERT LORIN,
28 *Administrative Patent Judges*.
29

30 APPEARANCES:

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1 The above-entitled matter came on for hearing on Wednesday, July 11,
2 2012, commencing at 10:00 a.m., at the U.S. Patent and Trademark Office,
3 600 Dulany Street, Alexandria, Virginia, before a Notary Public.

4
5 P R O C E E D I N G S

6 USHER: Good morning. Calendar number two -- or, rather, 2010-
7 5832, Mr. Covert [spelled phonetically].

8 JUDGE SCHAFFER: Okay. Let's go on the record. Okay. This is
9 appeal number 2010-005832 involving application serial number 10/801951.
10 And we have Mr. Covert arguing on behalf of the applicants today. Mr.
11 Covert, we realize there's outstanding petitions that have not been decided,
12 but, please, give your argument and refute [sic] to -- you know, you can refer
13 to whatever evidence that you feel that you need to refer to.

14 JOHN COVERT: All right. Thank you, Judge Schaffer. May it please
15 the board, sitting with me today is Marsha Rose Gullitine, my partner at the
16 firm and partner on this case. We're here to appeal the examiner's final
17 decision that our claims were rejected for obviousness type double patenting
18 over an earlier 102 patent. We believe the examiner erred in terms of fact and
19 law in three significant respects. They misconstrued the claims of the prior
20 patent, they misread the specification of the prior patent, and ignored two 132
21 declarations in reaching his conclusion that our claims are obvious in claim to
22 the earlier patent.

23 The claims of the pending application are directed to a method of
24 treating the microbial infection in an animal. Claims require administration
25 of a compound or an oligomer or polymer [unintelligible] the two. As the
26 board has noted, it's a very broad class of molecules. The claim also requires

1 that the composition be administered in an effective amount to actually treat a
2 microbial infection in an animal. And so, we believe that the claim, you
3 know, requires actual treatment of a microbial infection in an animal.

4 The claims of the 102 patent are directed broadly to oligomers and
5 polymers, that polymers have a broader size range and the patent kind of
6 contemplates using larger polymers and oligomers. The utility asserted in the
7 102 patent is kind of a contact microbicide, surface microbicides, and so the
8 invention in that 102 patent was really directed towards coming up with the
9 oligomers or polymers that could be used as coatings or imbedded in
10 inanimate objects. It could be used to coat or make plastics or polymers,
11 fabrics, coat glass -- utility would be in such things as medical devices,
12 surgical instruments, surgical gowns, treating walls in hospitals.

13 And, so, the idea of the 102 patent really is to construct these synthetic
14 polymers that behave in a manner based on kind of how natural antimicrobial
15 peptides or proteins work in nature to be a new class of microbicidal
16 compounds. And, you know, subsequently, the inventors discovered that as
17 you kind of zeroed down and lowered the molecular weight of these
18 molecules, they could be employed to treat animals. They could be used in
19 vivo [spelled phonetically] to treat infections. And that was a new discovery.
20 And, you know, our argument is that the 102 patent doesn't, you know,
21 doesn't disclose, suggest, provide any reason to one of ordinary skill in the art
22 to treat infections in an animal. It was clearly kind of a surface --

23 JUDGE SCHAFER: Well, why wouldn't this be -- you know, because
24 when I was reading it it occurred to me why wouldn't this be obvious to try
25 once you have these compounds that first were recognized -- they have some
26 sort of microbial killing effect. I mean, you have a huge class of them, also.

1 But wouldn't -- why wouldn't it be obvious to try them on a substrate that was
2 a living substrate? And one of the problems that I'm seeing was with -- that
3 the examiner was having was in the 102 patent there's an extremely broad
4 statement of what you mean by substrate. I mean, you argue that it's the same
5 animate stuff, but the definition doesn't seem to -- that you actually have in
6 there in, I think, in at least two locations is extremely broad.

7 JOHN COVERT: Well, I think if you go ahead and look closely at the
8 definitions in the 102 patent, nowhere does it mention kind of placing these
9 compounds on an animal. There is a mention of testing for toxicity of the
10 compounds. Part of that is that the natural antimicrobial polypeptides in the
11 past have been kind of looked at, and there was a big toxicity problem with
12 kind of the way these molecules functioned. And, so, the 102 patent, to the
13 extent it kind of teaches kind of anything related to animals or humans, one
14 there's kind of a suggestion that you avoid kind of using smaller molecular
15 weight materials that may leach and come in contact with living organisms,
16 and, two, there's a suggestion that you test kind of these kind of molecules to
17 make sure that they're not overly toxic to animals.

18 JUDGE MOORE: Well, I guess I'm a little curious as to why do I care
19 so much in terms of patentability that it's toxic? I know it's going to do what
20 the patent claim says. Why did -- I mean, it may hurt and/or kill the
21 underlying organism, but it will have killed the infection, will it not?

22 JOHN COVERT: I don't know if that's, you know -- maybe it will be,
23 you know, as far as you go possibly obvious to try that, but you don't know
24 whether it's going to kill the infection or not. I mean, the infection is kind of,
25 you know, it's kind of -- the microbes kind of getting into living tissue and
26 breeding. And, so, kind of contacting --

1 JUDGE MOORE: But my -- the reason I'm asking the question is
2 some of your arguments are couched in term safe and effective, and that's not
3 really the standard we use here. That's more of an FDA regulatory standard.
4 And, so, that takes a little bit of bite out of what you're arguing to me. I
5 mean, yeah, it might be toxic, it might hurt the organism, but it still is killing
6 the microorganism, as it were.

7 JOHN COVERT: Mm-hmm, and I think, you know, one thing we
8 looked at was, you know, there are other things that, you know, soap is a
9 topical microbicide. I mean, it's something that you use to kill germs.
10 Alcohol, the solutions that, you know, are in bottles everywhere now is a
11 topical microbicide. You don't necessarily kind of treat infections with kind
12 of a topical microbicide. Silver is employed sometimes in surgical
13 instruments -- you can embed it in the surgical instruments and it'll keep
14 microorganisms from growing on the surface. But you don't necessarily take
15 silver and administer an effective amount to treat an infection in an animal.

16 And so, you know, I think our argument is is, you know, there's really -
17 - there's no reason to go ahead and take the next step, and then there's, you
18 know -- I think what our declarance [spelled phonetically] kind of really kind
19 of hammer home at is that there's really -- there's not a reasonable explanation
20 that you can successfully employ these molecules as, you know, kind of
21 pharmaceutical agents to administer to animals and treat an infection.

22 JUDGE MOORE: Because of the length of the polymer chain?

23 JOHN COVERT: I think, you know, one -- if you look, you know --
24 that's one of our arguments is that the class in this patent is circumscribed --
25 the Claim 16 has a limit -- upper limit of 20 kind of M units. Claim 17 goes
26 to 1 to 10 M units. Claim 46, I think, is 1, 2, or 3 M units. And, so, we've

1 kind of progressively focused down and gotten much smaller on the oligomer
2 size, and, you know, ended up with something in a molecular weight range of
3 600 to 2,000 and not kind of the larger molecules. And the 102 patent, you
4 know, does have a disclosure that indicates that, you know, you want to avoid
5 kind of that lower molecular weight range because of this possibility of
6 leaching.

7 JUDGE SCHAFFER: Well, what is it -- where is it in the patent that
8 would suggest one away from the lower end? I mean, your claims -- you
9 have claims that, I think, are -- 2 to 30 or 3 to 30, I don't remember what the
10 exact lower range is. I mean, they're not -- and they're -- I recognize they're
11 not claims relied upon by the examiner specifically in there.

12 JOHN COVERT: And the examiner does point out that we do have a
13 claim with a -- you know, a repeating M unit of 2 to 30. But, you know, so
14 there is --

15 JUDGE SCHAFFER: And the purpose of all these compounds is to kill
16 the microbe. You know, for all of the compounds that you disclose -- and that
17 are disclosed in the 102 patent, they're all -- you know, and then that full
18 range of all that stuff that falls within the scope of the claims, they all, you
19 know, represented to be kill microbes.

20 JOHN COVERT: Right. And, you know, our argument is, you know,
21 they represent the kill microbes as part of something that you lay down on the
22 surface of an object, or you embed in the object while you're making the
23 object. And, so, Column 5, Lines 55 to 59 of the printed patent --

24 JUDGE SCHAFFER: Okay, let me look at that.

25 JOHN COVERT: -- is the disclosure related to...

26 JUDGE SCHAFFER: So, that's the last paragraph in Column 5, correct?

1 JOHN COVERT: That's where, you know, the 0.8 kilodaltons to 20
2 kilodaltons are more prone to leach from the surface of the substrate.

3 JUDGE SCHAFER: And then that's where the declaration testimony
4 comes in, saying -- I guess that says that in -- these would represent the lower
5 range of the length of the molecule? And so that's the teaching away aspect
6 of it?

7 JOHN COVERT: Mm-hmm. And so that's the molecular weight of
8 800 to 20,000 daltons. And, you know, specifically the Bermudas
9 Declaration, Paragraph 8, is -- kind of talks to that point.

10 And so, you know, our main position is that, you know, really kind of
11 this use disclosed utility as a surface microbicide just doesn't automatically
12 translate into, you know, kind of disclosing or suggesting the use of these
13 molecules to administer an infection in an animal.

14 JUDGE SCHAFER: Yeah, and I know I -- I'm looking at the
15 Bermudas Declaration, and he says that it's in his opinion that one skilled in
16 the art would not necessarily -- one wouldn't recognize that it would
17 necessarily be effective when administered to an animal. Well, is that the test
18 necessarily [unintelligible] --

19 JOHN COVERT: I'd like to test --

20 JUDGE SCHAFER: Isn't it, you know, reasonable likelihood rather
21 than necessarily? That seems to be to me a more stringent test you're urging
22 than what we apply in obviousness.

23 JOHN COVERT: Well, also, the test is reasonable expectation of
24 success, and, you know --

25 JUDGE SCHAFER: Well, necessarily and reasonable expectation -- if
26 you said necessarily is 100 percent, you could say, well, if somebody said,

1 well, 95 percent certainty, I mean, somebody could still say, "Well, that's not
2 necessarily." A 95 percent certainty doesn't mean it would necessarily imply
3 that. You know, so, there's a difference in that, you know, the reasonable
4 likelihood of success versus what the declarant [spelled phonetically] is
5 saying that you wouldn't necessarily expect. I don't think -- why is that the
6 standard necessarily expect it to work?

7 JOHN COVERT: You know, I -- you know, our argument is that, you
8 know, we're taking kind of language that this scientific kind of person that
9 works in the field feels, you know, comfortable, you know, putting forth.

10 JUDGE SCHAFER: Yeah, but obviousness is a question of law.

11 JOHN COVERT: Of law. Mm-hmm.

12 JUDGE SCHAFER: So, we've got to apply the legal standards to those
13 facts. And he seems to have, you know, he seems to somewhat overstated the
14 case. I mean, if you would have said it wouldn't, you know, one skilled in the
15 art wouldn't think it would be likely that these things would work, you know,
16 that's sort of more in the ballpark, I would think. But that's the question that I
17 have. You know, you can comment on it if you -- or not if you want.

18 JOHN COVERT: Yeah. I, you know, we kind of reread that -- his
19 statements as being equivalent to, you know, not providing a reasonable
20 expectation of success.

21 JUDGE SCHAFER: Okay.

22 JUDGE LORIN: Well, let me see if I can summarize a little bit of what
23 you said. I think you looked at this prior art claim and you said that it leads
24 you to the surface, right -- the surface of the substrate. And that would not
25 lead to one of ordinary skill to go in an animal. Is that what I heard you say?

26 JOHN COVERT: Right. And, so, to -- into the tissue of an animal to

1 treat an infection. And, so, you know, it's one thing to kill microbes that are
2 just sitting on a surface. It's another to kill microbes that are within a tissue
3 and kind of living within that tissue.

4 JUDGE SCHAFER: Well, your spec says that it can be topically
5 applied, that it can be a topical thing, and I think that's what the examiner was
6 getting at was that, you know, would be obvious to apply it to the, for
7 example, to the skin of an animal that needed treatment.

8 JOHN COVERT: And I think your -- there's still a difference between
9 topically applying a solution to kind of kill microorganisms that just happen
10 to be present on the skin of an animal and topically applying something that's
11 going to go into the tissue and stop an infection.

12 JUDGE LORIN: Yeah, and the examiner also said that it would have
13 been obvious to apply to the internal organs of an animal.

14 JOHN COVERT: And so, you know, I mean, just --

15 JUDGE LORIN: That would be in the animal.

16 JOHN COVERT: And, you know, I think that's taking, you know, a
17 very big step from, you know, talking about a patent that's coating inanimate
18 surfaces and substrates and killing microorganisms on the surface to then take
19 it, you know, the next leap forward and say that you can go internally and put
20 this on the surface of an organ and expect to treat an infection.

21 JUDGE LORIN: Yeah. It's the word "in" that's the problem here.

22 JOHN COVERT: Pardon me?

23 JUDGE LORIN: It's the word "in" that's the problem here. That's the
24 issue is a substrate [unintelligible] could be anything.

25 JUDGE MOORE: It's just administering the compounds.

26 JUDGE LORIN: The microorganisms are killing in both instances. It's

1 a microbial in both instances. Same chemical. The substrate is so generic it
2 could cover anything, including skin. The question is going into the animal.
3 That's where the issue is, isn't it?

4 JOHN COVERT: Yes, because, you know, an infection necessarily --
5 even an infection in your skin is -- in the animal, it's in the tissue. It's in and
6 among the cells. It's, you know --

7 JUDGE LORIN: So you --

8 JOHN COVERT: Microorganisms are there, and they're growing, and
9 they're establishing themselves whereas, you know, we have microorganisms
10 everywhere, and we can wipe the desk clean and kill them, but that's a
11 different thing than, you know, stopping or treating an infection in an animal
12 that's --

13 JUDGE LORIN: Yeah. Well, what I understand you're saying is it
14 would not have been obvious to one of ordinary skin [sic], but if you knew to
15 apply this compound topically that it would not have been obvious to then
16 administer it internally.

17 JOHN COVERT: Well, you know, we're making that argument, but I
18 think that we're going the next step as well and indicating that, you know, the
19 word substrate, when you read substrate in view of the 102 patent, there's no
20 indication that substrate refers to placing it onto kind of an animal, skin or an
21 organ or anything else. I mean --

22 JUDGE SCHAFER: Well, why, you know, that -- if it was never
23 contemplated to broadly cover placing it on any substrate, because you give a
24 very broad definition of substrate -- why wasn't there -- if it wasn't
25 contemplated to be on any substrate, why wasn't there something say -- well,
26 we don't mean that to imply a living -- applying it to a living organism? I

1 mean, your preferred -- clearly your preferred embodiment is to inanimate
2 objects, but you have a definition that encompasses that and also was very
3 broad. And, in the way patent attorneys always do, they draft their claims and
4 their specifications very, very broadly to sweep in as much as they can.

5 JOHN COVERT: And I guess I would disagree that substrate is
6 defined that broadly. I mean, it's, you know, to the extent that substrate is
7 discussed, you know, all of the disclosure that kind of illuminates substrate is,
8 talks about surfaces, talks about materials. Nowhere does it indicate that
9 you're -- we're talking about putting it onto the skin or any surface of a living
10 organism other than, you know, contacting it with the microbes themselves.

11 JUDGE LORIN: You're not saying that someone reading this claim
12 wouldn't look at the word substrate and not include in that genus skin or
13 flesh?

14 JOHN COVERT: I'm saying that it's a reasonable interpretation of that
15 issued claim that that claim would not cover kind of putting, you know,
16 treating -- I believe it doesn't cover treating an infection in an animal.

17 JUDGE LORIN: Yes. No, I understand where you're going with that.

18 JOHN COVERT: And, you know, the 102 patent to the extent that,
19 you know, we could have said, you know, could have been written to say, you
20 know, it doesn't include contacting skin, you know, there's nothing in there
21 that kind of indicates that you would put it onto the surface of a living
22 organism, that you would kind of use it to treat or apply to skin. You know,
23 all of the description in the specification really relates to, you know, paints
24 and caulks and making fibers and fabrics and, you know, really doesn't have
25 the type of disclosure that would suggest that the inventors in the 102 patent
26 contemplated applying those compounds to living organisms.

1 JUDGE SCHAFER: Well, the issue in cases like this is not necessarily
2 what the inventor's contemplated, it's what the patent attorney in writing,
3 trying to write up the inventor's contemplation -- we know that from
4 experience that these tend to get broadened out. And the various ones of us
5 that are at the board that worked on the outside will tell us how they tried to --
6 the applications are tended to be written broadly. And you do have the
7 definition here, and it says -- one of them, it says the facially amphiphilic
8 polymer may be attached to, applied on, or incorporated into almost any
9 substrate -- almost any substrate, including but not limited to -- and then you
10 listed a bunch of, you know, various inanimate -- woods, papers, synthetic
11 polymers, which indicates to me that it's -- the substrate is a very broad term.

12 JOHN COVERT: And, so, you know, one -- you know, we looked at
13 substrate as kind of being an inanimate surface, you know. Secondly, you
14 know, even if we offer the broader interpretation that substrate could be
15 anything that takes us to, you know, the inquiry of whether somebody would
16 reasonably expect that applying this to a substrate, which would be the skin or
17 an internal organ, would be reasonably expected to treat an infection in an
18 animal.

19 JUDGE MOORE: What evidence is relied upon in that opinion?

20 JOHN COVERT: In our --

21 JUDGE MOORE: Can you point me to some actual evidence, or is that
22 really his opinion more than anything?

23 JOHN COVERT: And this is -- you're talking about the 132
24 declarations?

25 JUDGE MOORE: Yeah. I think Mr. Bermudz?

26 JOHN COVERT: We've got Bermudz and Nicolau [spelled

1 phonetically].

2 JUDGE MOORE: I'm not sure how to pronounce that -- testifies that
3 the molecules at the shorter end would not necessarily be effective to treat an
4 animal with the microbial infection. What is that based on?

5 JOHN COVERT: You know, based on the -- that's, you know, based
6 on his experience in the art, I think it's based on -- can you -- what paragraph
7 are you pointing to? I'm sorry.

8 JUDGE MOORE: You would make me do this. It may take me a
9 minute to find it electronically.

10 JOHN COVERT: I know Paragraph 8 kind of refers to kind of the
11 leaching and -- but that's more directing towards the larger units.

12 JUDGE MOORE: Right. But that would affect -- and, actually, that
13 raised a good question from my point of view. Leaching doesn't necessarily
14 affect efficacy, does it, in terms of -- one would think that if the active agent
15 leached out into surrounding zones, it might actually help treatment of the
16 underlying infection. I -- so I guess I had a question as to regards to that.

17 JOHN COVERT: I think when you read the 102 patent, you know,
18 there was still a concern that these molecules would have a toxic effect to
19 kind of animals or the nature and surrounding area. And so, this teaching
20 was, you know, make these oligomers and polymers larger, avoid the leaching
21 issue, and avoid any possible toxicity issues.

22 JUDGE MOORE: Treat the kitchen table, but don't get it on the food?
23 Okay.

24 JOHN COVERT: Right. And so, you know, when you read the 102
25 patent as a whole, you know, it -- I think it kind of goes towards this use of
26 treating an animal was there was still this concern at the time of the filing of

1 the 102 patent that, you know, you would have these toxicity issues with the
2 animals. And, so, it was good as a topical microbicide or a contact
3 microbicide, but it really didn't give you this expectation that you could go
4 ahead and employ this as an antibacterial agent and treat infections. And, you
5 know, kind of what we have seen, you know, and part of this ends up in the
6 declaration on the Markush issue is these compounds have ended up being
7 kind of fabulous antimicrobial agents. There's a number of grants,
8 government-sponsored grants by the NIH, by the military.

9 These molecules are being used in a number of different applications
10 where, you know, for treatment of the kind of antibiotic resistant kind of
11 microbes. So these really kind of have turned out to be kind of special
12 molecules. And, of course, you know, it's kind of difficult. This is a generic
13 claim that we're presenting here, and it would be hard to come in with kind of
14 additional data to try to support the genus of Claim 16 with unexpected
15 results.

16 JUDGE MOORE: I can see that problem.

17 JOHN COVERT: But, you know, it -- they really kind of have turned
18 out to be, you know, very good molecules, and based on a pretty neat
19 discovery that, you know, that kind of -- that migrated from basically this
20 discovery of something that they thought they could make surgical
21 instruments and gowns out of and, you know, eventually got to the point
22 where the idea of treating infections came through.

23 And that, you know, to me that's kind of the argument against why
24 didn't you -- this claim kind of skin surfaces [spelled phonetically], you know,
25 well, why didn't they include it if it just didn't seem at the time that this would
26 apply itself to be a useful kind of invention to treat infections in an animal at

1 the time of the 102 patent?

2 JUDGE SCHAFER: Okay. Thank you. I think we understand your
3 position.

4 JOHN COVERT: All right.

5 JUDGE SCHAFER: And the case is submitted.

6 JOHN COVERT: No questions on Markush?

7 JUDGE SCHAFER: No, none. You didn't offer any argument, so...

8 JOHN COVERT: All right. Thank you for your time.

9 JUDGE SCHAFER: Off the record.

10 (Whereupon, the proceedings were concluded.)